K102327

APR 13 2012

510 (k) Summary

April 11, 2012

1. Company and Correspondant Making the Submission:

Name: JPI Healthcare Co,. LTD
Address: Woolim e-BIZ center #608
170-5, Kuro-3-dong, Kuro-gu
Seoul, 152-769
Telephone: +82-2-2108 - 2580 (Ext. 500-504)
Fax: +82-2-2108-1180
Contact: John Lim
Website: http://www.jpi.co.kr/

2. Identification of Device

Classification Name: Stationary X-ray System
Common Name: Digital Radiography X-ray System
Trade/Proprietary Name: Clear Vision DR7000F

3. Predicate Device

Manufacturer:	Choongwae Medical Corporation
Device:	CXD-DR80D
510(k) Number:	K083640 (Decision Date Jul 29, 2009)

Manufacturer:	Samsung Mobile Display Co., Ltd
Device:	LTX240AA01-A
510(k) Number:	K090742 (Decision Date Sep 18, 2009)

Manufacturer:	Samsung Mobile Display Co., Ltd
Device:	LLX240AB01
510(k) Number:	K102587 (Decision Date Dec 01, 2010)

4. Product Classification Names and Citations

Regulatory Number:	21 CFR 892.1680
Regulatory Class:	II
Product Code:	90 MQB

5. Description:

The Clear Vision DR7000F system is a high-resolution digital imaging system

designed for digital radiography. It is designed to replace conventional film radiography techniques. This system consists of a tube head/collimator assembly mounted on a U-Arm, along with a generator, generator control, and a detector, operating software.

The detector which is used proposed device is LTX240AA01-A (K090742) and LLX240AB01 (K102587) of Samsung Mobile Display Co., Ltd. These detectors are cleared by FDA 510(k).

6. Indication for use

The Clear Vision DR7000F product is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

The Clear Vision DR7000F system is intended to be used in medical clinics and hospitals for emergency, orthopedic, chiropractic, and other medical purposes. This device is not indicated for use with mammography.

7. Comparison with Predicate Device:

JPI Healthcare Co., Ltd, believes that the Clear Vision DR7000F is substantially equivalent to the CDX-DR80D of Choongwae Medical Corporation and the LTX240AA01-A, LLX240AB01 of Samsung Mobile Display Co. Ltd.

8. Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-1-1, EN/IEC 60601-1-3, EN/IEC 60601-2-7, EN/IEC 60601-2-28 and EN/IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2007). All test results were satisfactory.
We have also provided performance and clinical testing for the X-ray detectors, as recommended by the FDA guidance document "Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices"

9. Conclusions:
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification JPI Healthcare Co., Ltd. concludes that Clear Vision DR7000F is safe and effective and substantially equivalent to predicate devices as described herein.

10. JPI Healthcare Co. Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JPI Healthcare Co., Ltd.
% Mr. William Little
Product Manager
JPI Healthcare Solutions, Inc.
52 Newtown Plaza
PLAINVIEW NY 11803

APR 13 2012

Re: K102327
Trade/Device Name: Clear Vision DR7000F/Digital Radiography X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB and KPR
Dated: February 7, 2012
Received: February 7, 2012

Dear Mr. Little:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102327

Device Name: Clear Vision DR7000F / Digital Radiography X-ray System

Indications for Use:

The Clear Vision DR7000F product is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column,. chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

The Clear Vision DR7000F system is intended to be used in medical clinics and hospitals for emergency, orthopedic, chiropractic, and other medical purposes. This device is not indicated for use in mammography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _N/A____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102327